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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/881,509	06/24/1997	DOLORES J. SCHENDEL	P564-7015	3145

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EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	37

DATE MAILED: 10/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/881,509	Applicant(s) SCHENDEL, DOLORES J.
	Examiner Amy M. DeCloux	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-7,26,45 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4-7,26,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *35* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
Applicant's after-final amendment filed 9-13-02 (Paper No. 34) is acknowledged and has ben entered. The outstanding objection to the Abstract and the 112 second paragraph rejection have been withdrawn in light of said amendment. However a new grounds of rejection has been applied.

Applicant's sequence submission filed 9-13-02 overcomes in part some of the requirements for sequence disclosures. However it is noted that page 7 of the specification contains sequences lacking SEQ ID NO: tags. Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 C.F.R. 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

Information Disclosure Statement

Document AE of Applicant's IDS has been considered only to the extent of its English language Abstract.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 4-7, 26, and 45-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The instant claims are indefinite in the recitation of the phrase "a sequence 3-4 of amino acids" recited in the third line of Part (a) of Claim 2.

4. The instant claims are indefinite in the recitation of "for the peptide component of the T cell receptor ligands" because it is not clear what peptides are intended or what the ligand for the T cell receptor is. Including that the T cells are specific for kidney carcinoma would overcome this rejection.

PLEASE NOTE: Adding functional language to base claim 2 will overcome the following rejections, wherein said functional language includes that a T cell receptor comprising a CDR3 region with the amino acid sequence of SEQ ID NO:23, specifically binds Kidney carcinoma cells.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

REINSTATED Claims 2, 4-7, 26 and 45-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid which codes for an alpha chain of the human T cell receptor comprising SEQ ID NO:23 where $X_1...X_n$ is one of the amino acid sequences recited in Part a) of Claim 2 of the instant application, a Fab, a single chain antibody, or soluble TCR fragments thereof , and a composition thereof, does not reasonably provide enablement for the broader recitation where $X_1...X_n$ are any amino acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. Besides the nucleic acid that encodes for a human T cell receptor comprising SEQ ID NO:23, where $X_1...X_n$ is one of the amino acid sequences recited in Part a) of Claim 2 of the instant application, a Fab, a single chain antibody, or a soluble TCR fragment, or composition thereof, the specification fails to provide sufficient guidance in determining if either a nucleic acid that encodes any amino acids designated by $X_1...X_n$, or a nucleic acid that encodes a CDR region that is at least 90% identical to the amino acid sequence of SEQ ID NO:23, will encode an alpha chain of a T cell receptor (TCR) with the desired specificity. Furthermore, while recombinant techniques are available, it is not routine in the art to screen large numbers of nucleic acids which code for a specific CDR3 where the expectation of retaining similar encoding function is unpredictable based on the instant disclosure. Detailed information regarding the structural and functional requirements of the CDR3 region of an alpha TCR specific for kidney carcinoma, as disclosed in the instant specification, other than the CDR3 sequences recited in Part a) of claim 2 of the instant application, is lacking. Also, recognition of a T cell epitope depends on the interaction of CDR3 with the MHC-peptide complex. Therefore, predicting that any nucleic acid that encodes any amino acids designated by $X_1...X_n$, that would maintain the desired specificity is well outside the realm of routine experimentation; thus a skilled artisan would require guidance, such as information regarding the sequence of derivatives and fragments which preserve the TCR specificity, in order to make and use polynucleotides, probes, vectors, host cells and recombinant methods in a manner reasonably commensurate with the scope of the claims. Thus, it would require undue experimentation of one skilled in the art to practice the claimed invention. In re

Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

6. REINSTATED Claims 2, 4-7, 26 and 45-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

In the instant case, the specification does not convey to the artisan that the applicant had possession, at the time of invention, of 1) a nucleic acid molecule which codes for an amino acid sequence with an equivalent recognition specificity, as achieved with a T cell receptor comprising a CDR3 region with the amino acid sequence of SEQ ID NO:23 for the peptide components of the T cell receptor ligands as recited in Part B) of Claim 2 and dependent claims or 2) a nucleic acid that encodes a CDR region that is at least 90% identical to the amino aicd sequence of Part (a) as recited in claim 47. SEQ ID NO:23 which is YCLXXXXXSARQLTF encompasses 5 residues denoted by "x" which can be any amino acid. Percent identity language also denotes that any 1 or 2 of the defined amino acids of SEQ ID NO:23 can be replaced in any combination with any amino acid. Peptide components of the T cell receptor ligands can encompass any number of amino acid sequences. Due to this broad definition of a CDR3 sequence comprising SEQ ID NO:23 and the broad number of Peptide components of the T cell receptor ligands, none of these peptides (with the exception of the peptides recited in part A) of claim 2 and dependent claims) meets the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See Vas-Cath, page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath, page 1116.). The skilled artisan cannot envision all the contemplated peptides that are components of the T cell receptor ligands, nor all peptides with an equivalent recognition specificity as achieved with a T cell receptor comprising a CDR3 region with the amino acid sequence of SEQ ID NO:23, or with 90% identity with the amino acid sequence of Part (a) as recited in claim 47. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
October 10, 2002

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